

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ST. JUDE MEDICAL, CARDIOLOGY
DIVISION, INC., ST. JUDE MEDICAL
SYSTEMS AB, and ST. JUDE MEDICAL
S.C., INC.,

Plaintiffs,

v.

VOLCANO CORPORATION,

Defendant.

C.A. No. 10-631-RGA

REDACTED PUBLIC VERSION

FILED JUNE 1, 2012

**PLAINTIFFS' RESPONSE BRIEF IN OPPOSITION TO VOLCANO'S
MOTION TO STRIKE THE EXPERT
REPORTS OF W. ANTHONY MASON AND DR. KHALIL NAJAFI**

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INTRODUCTION

Volcano seeks to delay having to defend against St. Jude's serious allegations of Volcano's inequitable conduct in the prosecution of its patents, now asking to have all discovery related to inequitable conduct delayed for a separate trial.¹ These serious allegations of Volcano's inequitable conduct are detailed, in part, in the Third Mason Report, which Volcano attached as Exhibit 3 to its brief, which will assist the Court in understanding what is at stake.

The request Volcano makes in its motion would delay the resolution of St. Jude's inequitable conduct defenses until well into the future. It would inefficiently delay the determination of related factual issues by creating a multi-year and duplicative litigation, since the same questions regarding whether certain prior art references invalidate Volcano's patents and whether Volcano derived its "inventions" from St. Jude and others would need to be determined twice—once for the patent validity trial and again (under the preponderance-of-the-evidence standard) for the inequitable-conduct trial. And it would delay final decision and the opportunity for appeal by either party. Yet Volcano has been unable to cite a single case for its proposition that discovery, summary judgment, and trial on inequitable conduct should only take place after a validity and infringement trial has been completed.

Volcano seeks to exclude a number of expert opinions. Volcano first seeks to exclude Mr. Mason's expert opinions on issues relating to Volcano's inequitable conduct during the prosecution of U.S. Patent No. 7,134,994 (the "994 Patent") because, it argues, Mr. Mason's opinions are untimely and Volcano is prejudiced by having to respond to the report. But the report relates to inequitable conduct and was served immediately after this Court allowed St. Jude's inequitable conduct allegations into the case. Prior to the Court allowing inequitable

¹ Although St. Jude opposes Volcano's request for relief, it notes that Volcano did not meet and confer prior to filing its motion, as required under the Local Rules, nor did it file the required averment of such a conference. *Cf.* D. Del. L.R. 7.1.1.

conduct into the case, Volcano had resisted any discovery on St. Jude's serious inequitable conduct allegations for six months, moving to strike any expert reports relating to inequitable conduct that were served in that time.

Volcano should not be surprised now that, once inequitable conduct was added to the case, St. Jude provided expert reports on it. Volcano contends that it "would never have consented to permit" St. Jude to add inequitable conduct if it knew that St. Jude would submit expert reports. (Br. at 19.) Volcano never consented, however – in fact, it resisted St. Jude's motion to amend to add these serious allegations up through the oral argument on this motion.

Moreover, St. Jude could not have submitted the report earlier because Volcano withheld critical documents that showed that REDACTED

And Volcano even consented on the record to allowing Mr. Mason to supplement his report to incorporate this new information.

Volcano also argues that Mr. Mason improperly opines about the "intent" of the inventors. This is incorrect. Instead, Mr. Mason interprets the technical documents exchanged between the named inventors.

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But he does not address whether the inventors intended to deceive the Patent Office; that is for the fact finder to determine.

In its motion, Volcano next moves to exclude Professor Najafi's inequitable-conduct opinion, but his opinion is likewise admissible. REDACTED

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As explained below, notwithstanding Volcano's assertion in its brief, it is common practice to have experts testify about technical matters relating to inequitable conduct.

For each of these reasons, Volcano's motion should be denied in its entirety.

ARGUMENT

I. MR. MASON'S REPORT IS ADMISSIBLE AND SHOULD NOT BE STRICKEN

A. Background of Volcano's '994 Patent

Volcano's '994 Patent covers a medical monitoring device used for invasive cardiovascular diagnosis and display. The patent generally encompasses both the software and hardware architecture of the device, including the use of a computer, software components, peripheral interface cards, drivers, and the graphical user interface. (*See* '994 Patent (Aldrich Decl.² Ex. 1), claim 1.) The '994 Patent was applied for on May 20, 2002. The inventors therefore had an obligation to disclose any known, material art from prior to that date. (35 C.F.R. § 1.56(a).)

² "Aldrich Decl." refers to the Declaration of Nicholas (Nika) F. Aldrich, Jr. in Support of Plaintiff's Objection to Volcano's Motion to Strike the Expert Reports of W. Anthony Mason and Dr. Khalil Najafi, submitted concurrently herewith.

B. Volcano's inequitable conduct regarding the '994 Patent.

Volcano's named inventors, Messrs. Hoseit and Alpert, knew about, but failed to disclose, multiple material prior art references during the prosecution of the '994 Patent. (D.I. 188, at Sixth Aff. Defense.) Among those references were a medical monitoring device called the SmartFlow, made by Florence Medical ("Florence") between 1999 and 2003, and Florence's related U.S. Patent 6,193,669 (the "'669 Patent," attached to the Aldrich Decl. as Ex. 2).

The SmartFlow was well known in the industry, having been shown at multiple medical conferences between 1999-2002. (Aldrich Decl. Ex. 3, ¶¶ 5, 8-18, & Ex. 4, ¶¶ 11-22). It was used by many U.S. doctors in 2001-2002 and was the subject of multiple press releases. (Aldrich Decl. Ex. 3, ¶ 4 & Ex. 4, ¶ 10.)

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Volcano and Florence Medical had an extensive history.

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Notwithstanding this knowledge, Volcano never disclosed anything about the SmartFlow to the PTO during prosecution of the '994 Patent.

C. Background of Mr. Mason's Expert Reports.

Mr. Mason is a computer expert with specialized expertise in the aspects of computer systems covered by the '994 Patent. He has served three reports in this case.

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D. Volcano consented to Mr. Mason writing a report based on Volcano's withheld Florence Medical documents

Notably, and notwithstanding St. Jude's repeated requests, Volcano did not produce any communications between Florence and Volcano during fact discovery, which closed November 4, 2011. (Aldrich Decl. ¶¶ 20-23.)

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Volcano did not produce those key documents before Mr. Mason's first expert report was due. (Aldrich Decl. ¶¶ 26-27.)

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St. Jude objected on the record to the surprise production of documents that had been repeatedly requested for over six months and further stated as follows:

If we send these documents to Mr. Mason and if he needs to add something to his report I think we reserve the right to do so. These should have been produced back in fact discovery, but you can proceed to question the witness about them.

(Aldrich Decl. ¶ 28.)

Counsel to Volcano responded on the record:

Mr. Rosen: . . . As we only recently discovered these, we have no problem if Mr. Mason wants to supplement or amend his report to incorporate them.

(Aldrich Decl. ¶ 29.)

Volcano only produced

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on April 18, 2012: *five months* after the emails were produced and long after fact discovery closed. (Aldrich Decl. ¶¶ 30-36.)

E. Background of Mr. Mason's Third Expert Report.

On April 4, 2012, this Court granted St. Jude's motion for leave to amend its pleadings to incorporate allegations of Volcano's inequitable conduct. (D.I. 181.) On April 13, 2012, Mr.

Mason served a third expert report (the "Mason 3d Report," attached to Volcano's moving papers at D.I. 208, Ex. 2)

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This analysis provides the finder of fact with an understanding of the meaning of the highly technical exchange within the documents. Technical experts are commonly and appropriately used to help the finder of fact in inequitable conduct cases. *See Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1252 (Fed. Cir. 2008)

³ *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) ("*Therasense*") (requiring "but for" materiality – that the patent would not have issued but for the non-disclosure of the prior art reference).

(finding that the district court erred by refusing to consider "testimony from qualified experts regarding whether [undisclosed] experiments had any bearing on any statutory ground for patentability"); *Alloc, Inc. v. Pergo, Inc.*, 366 F. App'x 173, 176 (Fed. Cir. 2010) (approving the district court's consideration of defendant's "technical expert's testimony" in drawing its conclusions with respect to inequitable conduct) (nonprecedential).

F. Mr. Mason's opinions about what the named inventors claimed they "understood" is admissible

Contrary to Volcano's assertions, Mr. Mason does not testify about the intent of the inventors. (*Cf.* Br.⁴ at 7-9.) He limits his opinion to what he is qualified to testify about as a technical expert – an interpretation of technical documents. For example, the parties agree that the patent requires the use of an extensible, modular software arrangement. (Aldrich Decl. Ex. 10.)

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Similarly, the patent claims the use of "kernel mode drivers that extract processed sensor data from a peripheral interface card." ('994 Patent (Aldrich Decl. Ex. 1), claim 1.)

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⁴ "Br." refers to Volcano Corporation's Brief in Opposition to Plaintiffs' Motion to Strike the Expert Report of Volcano's "Patent Law Expert" and Cross-Motion to Strike Expert Reports of St. Jude's Inequitable Conduct Experts (D.I. 207).

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It is proper for a technical expert to review and use opposing party documents for the factual underpinnings of his technical opinion. *See LG Electronics U.S.A., Inc. v. Whirlpool Corp.*, 2010 WL 3397358, at *6 (N.D. Ill. Aug. 24, 2010) ("If the factual underpinnings of Dr. Rao's expert testimony regarding causation are weak that is a matter not for exclusion, but as the Supreme Court stressed in *Daubert* for "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof "), and cases cited therein. Since Volcano is free to cross-examine Mr. Mason on these underlying facts, Mr. Mason's use of these facts cannot be grounds for exclusion.

Moreover, this is the same level of "awareness" that Volcano says its own patent law expert will testify about. For example, in the same brief in which it opposes Mr. Mason's technical opinions about what the inventors admitted they were "aware" of, Volcano states that

"Mr. Nixon's Testimony in This Case Will Be Helpful to the Trier of Fact," and continues that, "[a]t trial, Mr. Nixon intends to [testify about] ... whether patent practitioners prosecuting applications would be aware of prior art references cited in other applications." (Br. at 4, 5-6.)

The cases cited by Volcano in support of striking Mr. Mason's opinions are inapposite. These cases stand for the proposition that an expert may not opine about an inventor's intent to deceive the PTO (Br. at 7-8) – a matter on which Mr. Mason does *not* opine. Instead, Mr. Mason only interprets technical documents to explain what the inventors admit they "understood" about the prior art when they had a duty to disclose it. Volcano has cited no cases relating to the admissibility of an expert's opinion about the interpretation of technical documents authored by the inventor relating to what the inventor "understood."

G. Mr. Mason does not provide any new invalidity opinions.

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First, Mr. Mason's new report does not offer a new invalidity opinion.

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Mr. Mason also reserved his right to supplement or amend his opinion, including if St. Jude's motion for leave to amend the complaint to incorporate inequitable conduct were granted. (*Id.* ¶¶ 519-521.) That leave has now been granted. (D.I. 181.) And Mr. Mason's opinions in his third expert report concern Volcano's inequitable conduct in prosecuting the '994 Patent.

Volcano resisted any discovery (including expert reports) on St. Jude's inequitable conduct claims for six months. First, Volcano opposed St. Jude's motion to amend its pleadings to allow it to plead inequitable conduct, arguing that St. Jude's allegations were untimely and futile. (D.I. 108 at 1.) Subsequently, at a hearing regarding a deposition of one of Volcano's named witnesses, Volcano objected to any fact discovery relating to St. Jude's inequitable conduct allegations, arguing that those allegations were not yet "in the case." (D.I. 113 at 20:6 – 21:8.) Then, after St. Jude submitted the Expert Report of Dr. Najafi when expert reports were due, Volcano moved to "exclude the expert report of Dr. Khalil Najafi, which pertains to St. Jude's allegation that Volcano committed inequitable conduct . . . [which] is not at issue in this case." (D.I. 131.)

Accordingly, Mr. Mason produced his inequitable conduct report immediately after St. Jude's motion to amend was granted. Volcano now seeks to exclude it because, it contends, the opinions in it should have been provided in his first report. The timing of Mr. Mason's report is the direct result of Volcano's refusal to allow any discovery relating to inequitable conduct – and its further withholding of key documents – until after Mr. Mason's first reports were produced. Moreover, Volcano consented on the record to allow Mr. Mason to write a supplemental report.

Additionally, there is no prejudice to Volcano. Mr. Mason's inequitable conduct report was produced nearly two weeks prior to his deposition. (Aldrich Decl. Ex. 12.) Volcano had the

opportunity to ask Mr. Mason about his opinions at his deposition, and Mr. Mason repeatedly referred to his inequitable conduct report as part of his opinions in this case:

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Additionally, the parties have already agreed that Volcano will have additional time to depose Mr. Mason about his opinions in his third expert report. However, Volcano's motion seeks to delay deposing Mr. Mason about his opinions until after this case's patent validity trial.

H. The authority cited by Volcano does not support its position.

The cases Volcano cited in support are either inapposite or actually support St. Jude's position. For example, *B. Braun Melsungen AG v. Terumo Medical Corp.*, 749 F. Supp. 2d 210 (D. Del. 2010) undermines Volcano's position. (*Cf.* Br. at 9.) In *Braun*, supplementations to an expert report were allowed with a summary judgment motion, after expert depositions were completed. (*Braun*, 749 F. Supp. 2d at 220.) The Court refused to impose the "extreme sanction" of striking the supplemental report. (*Id.* at 221.)

Additionally, *Bridgestone Sports Co. v. Acushnet Co.*, No. 05-132 JJF, 2007 WL 521894 (D. Del. Feb. 15, 2007), also cited by Volcano, does not address expert opinions, and instead excludes prior art first identified four months after a court-ordered deadline. (*Id.* at *3.) None of Volcano's other cited cases address an expert report served on an issue immediately after the issue was admitted into the case, and also do not address a situation where the party seeking exclusion resisted any discovery on the issue up to that point. (*See, e.g.*, Br. at 9 (citing *D&D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, 2009 WL 6315315, at *1 (D.N.J. Feb. 27, 2009) (precluding an expert report filed in support of amending a complaint that had been denied three times prior); *Flickinger v. Toys R Us, Inc.*, 2011 WL 3359646, at *1, *2 (M.D. Pa. Aug. 3, 2011) (denying new expert reports served immediately before trial, six months after they were due)).)

I. Mr. Mason's remaining opinions are not duplicative.

Finally, Mr. Mason provides other opinions that relate specifically to Volcano's inequitable conduct, but which Volcano complains are duplicative of his prior reports. If they were duplicative, then these opinions certainly cannot prejudice Volcano. But of course these opinions are not duplicative, which is why Volcano seeks to exclude them.

For example, in order to prove that the SmartFlow, the '669 Patent and the RadiAnalyzer would have been material to the PTO during the prosecution of the '994 Patent, St. Jude needs to prove that the patent would not have issued but for the failure to disclose those references. (*Therasense*, 649 F.3d at 1291-92.) When opining about whether a patent would have issued over prior art pursuant to 35 U.S.C. § 102(a), it is necessary to determine the date of the alleged invention. The date of the invention is the date that the invention was conceived, followed by a diligent reduction to practice by the inventors. (*Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996).)

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This opinion is directly related to his inequitable conduct opinion and is not duplicative of any opinion in his Opening Report.

In his inequitable conduct report,

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Additionally, Volcano only produced key technical documents related to the SmartFlow for the first time after Mr. Mason's Opening Report was served. (Aldrich Decl. ¶¶ 20-37.)

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Mr. Mason could not have provided these opinions in his Opening Report because Volcano withheld these highly relevant documents.

II. DR. NAJAFI'S REPORT IS ADMISSIBLE AND SHOULD NOT BE STRICKEN

A. Background

Volcano's '965 Patent relates generally to the structure of a pressure-sensing intravascular guide wire with an ultraminiature pressure sensor mounted in a housing in its distal portion. (Aldrich Decl. Ex. 14.) Volcano accuses St. Jude of infringing the '965 Patent. In addition to St. Jude's non-infringement position, St. Jude alleges that the entire family of patents related to the '965 Patent is unenforceable due to Volcano's inequitable conduct during the lengthy prosecution of the patent family, including the filing of multiple false affidavits with the PTO and the failure of the inventors to disclose a number of material prior art references to the PTO. (D.I. 188.)

Dr. Najafi's report (D.I. 208 Ex. 5) relates directly to the first patent in the family, U.S. Patent 5,715,827 (the "'827 Patent," attached to the Aldrich Decl. as Ex. 15.), the great-

grandparent of the '965 Patent. Dr. Najafi's conclusions apply to the prosecution of the '965 Patent under the doctrine of infectious unenforceability. (*See Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 809-12 (Fed. Cir. 1990); *see also* Aldrich Decl. Ex. 16, § V.) In the '827 Patent, the named inventors claimed an invention for a pressure sensor. Claim 1 is representative, and recites a guide wire .018" or less, having a

pressure sensor comprising a crystal of semiconductor material having a well therein and forming a diaphragm having a thickness ranging from 2 to 5 microns, . . . a backing plate formed of an insulating material bonded to the crystal . . . said well being formed so it extends through said one side together with troughs formed in the crystal of semiconductor material and opening on the opposite side of the crystal of semiconductor material, conductive means including leads secured in said troughs and means in said troughs for establishing electrical connections between the leads in the troughs and the first and second diffused portions.

('827 Patent (Aldrich Decl. Ex. 15), claim 1.)

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B. Dr. Najafi's opinions in Sections I-IX are relevant to the issue of inventorship

To provide technical expertise on the topic of inventorship, St. Jude retained Professor Najafi, a leading expert on pressure sensors. Dr. Najafi explains in his short report the meaning of the features claimed in the '827 Patent and the effort that would have been required to develop such a pressure sensor. (Najafi Report §§ VI, IX.)

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Volcano mischaracterizes the report and contends that Knutti and Allen only "designed" a non-novel pressure sensor. (Br. at 14-16.)

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(*Id.* ¶¶ 50-51.)

Additionally, Volcano states that Dr. Najafi never discusses conception. (Br. at 15 ("Dr. Najafi's analysis never once discusses the conception of the inventions actually claimed in the

'827 patent . . .").)

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C. Dr. Najafi's opinion in section X will be helpful to the trier of fact on the issue of inventorship

Volcano seeks to strike Section X of the Najafi Report by arguing that it merely restates the contents of a factual declaration. (Br. at 17.) To the contrary, Section X is admissible as the factual predicate for his opinion that

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An expert

can always state the factual predicate for his opinions; Volcano cites no case stating otherwise.

D. Dr. Najafi's opinion relates to the '965 Patent.

Volcano suggests that Dr. Najafi's opinions are also irrelevant because "the '827 Patent is not asserted in this case." (Br. at 15.) But Volcano ignores the doctrine of infectious unenforceability. Here, the '827 Patent made it possible for Volcano to add new claims during the '965 Patent's prosecution that could not have been added otherwise, and thus the inequitable conduct in the '827 Patent infected and tainted the '965 Patent's prosecution. (D.I. 188 at Third Affirmative Defense.) In other words, but for Volcano's inequitable conduct during the '827 Patent's prosecution, Volcano could not have filed the '965 Patent as a continuation application. (See generally Second Expert Report of John Love § V, attached to the Aldrich Decl. as Ex. 16.)

Moreover, the claims in the '965 Patent as filed were nearly identical to the improper claims in the '827 Patent, and the two patents have nearly identical specifications. (*Id.*; see also *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580, 595-96 (D. Del. 2006) ("strikingly

similar" specifications and "closely related" claims justified infectious-unenforceability finding).)

III. INEQUITABLE CONDUCT DISCOVERY SHOULD BE COMPLETED NOW

Discovery concerning Volcano's allegations of inequitable conduct is nearly complete. While Volcano was able to complete its inequitable-conduct discovery, it seeks to delay St. Jude's discovery concerning Volcano's inequitable conduct, only recently added to the case by the Court, until after trial.

But this delay is unnecessary. St. Jude has served all of its inequitable conduct expert reports, subject to its right to amend or supplement. Volcano may now serve its responsive reports and depositions of the experts can be taken. Discovery continues on issues relating to infringement and validity. The parties have agreed that St. Jude will have another opportunity to depose Mr. Hicks (Aldrich Decl. Ex. 33), and Volcano has requested additional time to depose St. Jude's expert, Dr. Bugay, and its own expert, Ian Ward. For many reasons, completing inequitable conduct discovery now is the better and more efficient approach:

First, there is no reason that inequitable conduct discovery should not proceed at the same time as the remaining validity and infringement discovery. Simultaneous discovery will streamline discovery by eliminating, for example, multiple additional depositions of Mr. Hicks.

Second, St. Jude's serious allegations of inequitable conduct are a defense to Volcano's infringement case, determination of which should not be unduly delayed. Volcano asserts that determination of Volcano's inequitable conduct may be mooted should this Court find that St. Jude does not infringe Volcano's patents. (Br. at 18.) To the contrary, determinations of Volcano's inequitable conduct will still be relevant to St. Jude's request for attorneys' fees spent defending against Volcano's inequitably prosecuted patents. (*Therasense*, 649 F.3d at 1289 ("prevailing on a claim of inequitable conduct often makes a case 'exceptional,' leading

potentially to an award of attorneys' fees under 35 U.S.C. § 285").) Moreover, St. Jude plans to move for summary judgment regarding Volcano's inequitable conduct. Having the inequitable conduct matters decided at summary judgment may moot the need for a trial on invalidity or infringement.

Finally, while inequitable conduct is ultimately a matter for this Court to decide, there are facts that overlap with the validity of the patents, especially under the new *Therasense* "but for" validity standard, which may be appropriate for a jury to consider, including whether the relevant prior art was material, what the named inventors knew, and when they knew it. Where there is substantial overlap between a jury's determination of "whether [Plaintiff] knowingly made a misrepresentation or omission to the PTO, whether the misrepresentation or omission was material, and whether [Plaintiff] acted with the intention of misleading the PTO" and an inequitable conduct allegation, the Court must accept the jury's determination. (*Cabinet Vision v. Cabnetware*, 129 F.3d 595, 600 (Fed. Cir. 1997); *see also Hebert v. Lisle Corp.*, 99 F.3d 1109, 1114 (Fed. Cir. 1996) ("Some courts have reserved the entire issue of inequitable conduct unto themselves; some have submitted special interrogatories to the jury on the facts of materiality and intent; and some have instructed the jury to find and weigh the facts of materiality and intent and decide the ultimate question of inequitable conduct"); *Isco Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 499-500 (D. Del. 2003) (adopting the jury's advisory conclusion of unenforceability for inequitable conduct) *aff'd*, 123 F. App'x 974 (Fed. Cir. 2005).)

Tellingly, Volcano has cited no case supporting its proposal to delay inequitable conduct discovery. Such an unusual schedule creating unnecessary delay should not be applied here.

CONCLUSION

For the foregoing reasons, St. Jude respectfully requests that the Court deny Volcano's motion in its entirety.

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**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I hereby certify that on May 24, 2012, I electronically filed the foregoing document with the Clerk of Court using CM/ECF, which will send notification of such filing to counsel of record, and have sent a true and correct copy by electronic mail to the following:

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